UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

In Re: Actos (Pioglitazone) Products Liability Litigation	)
This Document Applies to: Lillian Davis, *et al*. v. Takeda Pharmaceuticals America, Inc., *et al.*, Case No. 6:12-cv-00133-RFD-PJH	) **6:11-md-2299**
	) **JUDGE DOHERTY**
	) **MAGISTRATE JUDGE HANNA**

ANSWER AND SEPARATE OR AFFIRMATIVE DEFENSES OF TAKEDA PHARMACEUTICAL COMPANY LIMITED TO PLAINTIFFS' CLASS ACTION COMPLAINT

Takeda Pharmaceutical Company Limited ("TPC"), by and through its attorneys, answers Plaintiffs' Complaint as follows:

NATURE OF THE ACTION

1. This action seeks to recover damages for injuries sustained by the Plaintiffs as the direct and proximate result of the wrongful conduct of the Defendants in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the widely-used diabetes prescription drug Actos (pioglitazone), and to establish a medical monitoring class that provides Plaintiffs, and all others similarly situated, with appropriate medical care for the current and/or latent injuries they sustained as a result of the prescription drug Actos.

ANSWER: TPC admits that Plaintiffs, through their counsel of record, have filed an action against Takeda Pharmaceuticals America, Inc. ("TPA"), Takeda Pharmaceuticals U.S.A., Inc., formerly known as Takeda Pharmaceuticals North America, Inc. ("TPUSA"), TPC (collectively, "Takeda"), and Eli Lilly and Company ("Eli Lilly"). TPC further admits that, pursuant to approval by the United States Food and Drug Administration ("FDA"), TPC has manufactured

ACTOS®, TPUSA has marketed ACTOS®, TPA has sold, distributed, and marketed ACTOS®, and Eli Lilly marketed ACTOS® from 1999 t0 2006 for prescription by licensed physicians in the United States. TPC denies the remaining allegations of paragraph 1.

2. Actos is a prescription medication used in the treatment of type II diabetes.

ANSWER: TPC admits that ACTOS® (pioglitazone HCl) is a prescription medication approved by the FDA for prescription by licensed physicians as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

3. Paragraph 3 was omitted from the Complaint.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000.00 exclusive of interest and costs. There is complete diversity of citizenship between the Plaintiffs and Defendants. Plaintiffs are residents of the State of Louisiana. All Defendants are corporations of states other than the State of Louisiana, and all Defendants have their principal place of business in a state other than the State of Louisiana.

ANSWER: TPC states that the allegations of paragraph 4 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 4 are construed as factual allegations directed to TPC, it admits that the amount in controversy exceeds $75,000, exclusive of interest and costs, and that this Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a)(1). TPC further admits that all Takeda defendants, and, on information and belief, Eli Lilly, are incorporated and have their principal places of business in states other than Louisiana, where Plaintiffs claim to reside. TPC lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 4.

5. This Court also has subject matter jurisdiction under the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because members of the proposed nationwide Class are citizens from States different from the corporate residence of each Defendant, and the aggregate amount in controversy exceeds $5,000,000.

ANSWER: TPC states that the allegations of paragraph 5 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 5 are construed as factual allegations directed to TPC, it admits that this Court has subject matter jurisdiction over this action. TPC lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 5.

6. This Court has personal jurisdiction over the Defendants, each of which is licensed to conduct and/or is systematically and continuously conducting business in this State, including, but not limited to, the marketing, advertising, selling, and distributing drugs, including Actos, to residents in this State.

ANSWER: TPC states that the allegations of paragraph 6 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 6 are construed as factual allegations directed to TPC, it admits that, pursuant to approval by the FDA, TPUSA has marketed ACTOS®, TPA has sold, marketed, and distributed ACTOS®, and Eli Lilly marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States, including the State of Louisiana. TPC denies the remaining allegations of paragraph 6.

7. Venue is proper in this District pursuant to 28 U.D.C. § 1391(a) because the defendant marketed, advertised, and distributed the dangerous product in this Federal District, and cause harm to Class members residing with the District. The Plaintiff resides in this Federal District and the damages occurred in this Federal District. The Defendants do substantial business in the State of Louisiana and within this Federal District, and at all times relevant hereto, the Defendants developed, manufactured, promoted, marketed, distributed, tested, warranted, and sold Actos in interstate commerce.

ANSWER: TPC states that the allegations of paragraph 7 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 7 are construed as factual allegations directed to TPC, it admits that, pursuant to approval by the FDA, TPUSA has marketed ACTOS®, has TPA sold, marketed, and distributed ACTOS®, and Eli Lilly marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States, including the State of Louisiana. TPC denies the remaining allegations of paragraph 7.

PARTIES

8. Plaintiff Lillian Davis is and was at all relevant times, an adult resident of the State of Louisiana. During the Class Period, she was prescribed Actos and did ingest Actos. Plaintiff has suffered damages as a result of Defendants' illegal and wrongful conduct described below.

ANSWER: TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 8 pertaining to plaintiff Lillian Davis's residence, prescription for, and ingestion of ACTOS®. TPC denies the remaining allegations of paragraph 8.

9. Plaintiff William Coxe is and was at all relevant times, an adult resident of the State of Louisiana. During the Class Period, he was prescribed Actos and did ingest Actos. Plaintiff has suffered damages as a result of Defendants' illegal and wrongful conduct described below.

ANSWER: TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 9 pertaining to plaintiff William Coxe's residence, prescription for, and ingestion of ACTOS®. TPC denies the remaining allegations of paragraph 9.

10. Plaintiff Barbara Davis is and was at all relevant times, an adult resident of the State of Louisiana. She is the spouse of William Coxe. Plaintiff has suffered damages as a result of Defendants' illegal and wrongful conduct described below.

ANSWER: TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 10 pertaining to plaintiff Barbara Davis's residence or spousal relationship. TPC denies the remaining allegations of paragraph 10.

11. Defendant Takeda Pharmaceuticals America, Inc. ("Takeda America") is a Delaware Corporation, which has its principle place of business at One Takeda Parkway, Deerfield, IL 60015.

ANSWER: TPC admits that TPA is a Delaware corporation with its principal place of business in Deerfield, Illinois.

12. At all times material to this lawsuit, Takeda America was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug Actos to the general public, including Plaintiff.

ANSWER: TPC admits that, pursuant to approval by the FDA, TPA sells, markets, and distributes ACTOS® for prescription by licensed physicians in the United States. TPC denies the remaining allegations of paragraph 12.

13. At all times material to this lawsuit, Takeda America was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; derive substantial revenue from goods and products used in the State of Louisiana; and supply Actos within the State of Louisiana.

ANSWER: TPC admits that, pursuant to approval by the FDA, TPA sells, markets, and distributes ACTOS® for prescription by licensed physicians in the United States, including the State of Louisiana, and that TPA has received revenue from the sale ACTOS® in the United States, including the State of Louisiana. TPC states that the phrase "substantial revenue" is vague and ambiguous. Accordingly, TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13 pertaining to same. TPC denies the remaining allegations of paragraph 13.

14. Defendant Takeda Pharmaceuticals North America, Inc. ("Takeda North America") is a Delaware Corporation, which has its principle place of business at One Takeda Parkway, Deerfield, IL 60015.

ANSWER: TPC admits that TPUSA is a Delaware corporation with its principal place of business in Deerfield, Illinois.

15. At all times material to this lawsuit, Takeda North America was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug Actos to the general public, including Plaintiff.

ANSWER: TPC admits that, pursuant to approval by the FDA, TPUSA markets ACTOS® for prescription by licensed physicians in the United States, including the State of Louisiana. TPC denies the remaining allegations of paragraph 15.

16. At all times material to this lawsuit, Takeda North America was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of

Louisiana; derive substantial revenue from goods and products used in the State of Louisiana; and supply Actos within the State of Louisiana.

ANSWER: TPC admits that, pursuant to approval by the FDA, TPUSA markets ACTOS® for prescription by licensed physicians in the United States, including the State of Louisiana, and that TPUSA has received revenue from the sale ACTOS® in the United States, including the State of Louisiana. TPC states that the phrase "substantial revenue" is vague and ambiguous. Accordingly, TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 16 pertaining to same. TPC denies the remaining allegations of paragraph 16.

17. Defendant Takeda Pharmaceuticals Company Limited ("Takeda Limited") is a foreign corporation, which has its principle place of business in Osaka, Japan.

ANSWER: TPC admits that it is a Japanese corporation with its principal place of business in Osaka, Japan.

18. At all times material to this lawsuit, Takeda Limited was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug Actos to the general public, including Plaintiff.

ANSWER: TPC admits that, pursuant to approval by the FDA, it has researched and manufactured ACTOS®. TPC denies the remaining allegations of paragraph 18.

19. At all times material to this lawsuit, Takeda Limited was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; derive substantial revenue from goods and products used in the State of Louisiana; and supply Actos within the State of Louisiana.

ANSWER: TPC admits that it has received revenue from the sale ACTOS® in the State of Louisiana. TPC states that the phrase "substantial revenue" is vague and ambiguous. Accordingly, TPC lacks knowledge or information sufficient to form a belief as to the truth of

the allegations of paragraph 19 pertaining to same. TPC denies the remaining allegations of paragraph 19.

20. Defendant Eli Lilly Company ("Lilly") is an Indiana Corporation, which has its principle place of business located at Lilly Corporate Center, Indianapolis, Indiana, 46285.

ANSWER: TPC states that the allegations of paragraph 20 do not state any allegations as to TPC and, therefore, no response by TPC is required. If a response is required, TPC admits, on information and belief, that Eli Lilly is an Indiana corporation with its principal place of business in Indiana.

21. At all times material to this lawsuit, Lilly was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug Actos to the general public, including Plaintiff.

ANSWER: TPC states that the allegations of paragraph 21 do not state any allegations as to TPC and, therefore, no response by TPC is required. If a response is required, TPC admits that, pursuant to approval by the FDA, Eli Lilly marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States, including the State of Louisiana. TPC lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 21.

22. At all times material to this lawsuit, Lilly was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; derive substantial revenue from goods and products used in the State of Louisiana; and supply Actos within the State of Louisiana.

ANSWER: TPC states that the allegations of paragraph 22 do not state any allegations as to TPC and, therefore, no response by TPC is required. If a response is required, TPC admits that, pursuant to approval by the FDA, Eli Lilly marketed ACTOS® from 1999 to 2006 for prescription by licensed physicians in the United States, including the State of Louisiana. TPC states that the phrase "substantial revenue" is vague and ambiguous. Accordingly, TPC lacks

knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22 pertaining to same. TPC lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 22.

FACTUAL ALLEGATIONS

23. At all relevant times, Defendants were and remain in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired the Defendant(s) who designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Actos for use as a prescription treatment for type II diabetes, to wit:

ANSWER: TPC admits that, pursuant to approval by the FDA, TPC has researched and manufactured ACTOS®, TPA has sold, marketed and distributed ACTOS®, Eli Lilly marketed ACTOS® from 1999 to 2006, and TPUSA has marketed ACTOS® for prescription by licensed physicians in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. TPC denies the remaining allegations of paragraph 23.

24. Actos is in a class of insulin-sensitizing drugs known as thiazolidinediones (TZDs) or glitazones. Actos is used to treat type II diabetes.

ANSWER: TPC admits that the FDA approved ACTOS® for prescription by licensed physicians in the United States as an adjunct to diet and exercise for the improvement of glycemic control in patients with type 2 diabetes as monotherapy or in combination with a sulfonylurea, metformin, or insulin. TPC also admits that ACTOS® is a member of a class of medications known as thiazolidinediones ("TZDs"). TPC denies the remaining allegations of paragraph 24.

25. Actos acts upon the insulin-sensitive genes involved in the control of glucose and lipid metabolism in muscle and the liver. As such, Actos is supposed to reduce insulin resistance; increase the body's expense of insulin-dependent glucose; decrease withdrawal of glucose from the liver; and reduce the amount of glucose, insulin, and glycated hemoglobin in the bloodstream.

ANSWER: TPC admits that pioglitazone is an agonist for peroxisome proliferator-activated receptor-gamma (PPAR*y*). PPAR receptors are found in tissues important for insulin action such as adipose tissue, skeletal muscle, and liver. Activation of PPAR*y* nuclear receptors modulates the transcription of a number of insulin responsive genes involved in the control of glucose and lipid metabolism. ACTOS® decreases insulin resistance in the periphery and in the liver, resulting in increased insulin-dependent glucose disposal and decreased hepatic glucose output. TPC denies any remaining allegations of paragraph 25.

26. Actos is used in Monotherapy and in combination with metformin (Actoplus Met, Actoplus Met XR) and glimepiride (Duetact).

ANSWER: TPC admits that, pursuant to approval by the FDA, pioglitazone HCl is marketed for prescription by licensed physicians in the United States as ACTOS®, in combination with metformin as ACTOplus Met® and ACTOplus Met XR®, and in combination with glimepiride as Duetact®.

27. The United States Food and Drug Administration ("FDA") approved Actos for the treatment of type II diabetes on July 15, 1999. From before its approval and thereafter, Defendants collaborated to design, research, manufacture, test, advertise, promote, market, sell, and distribute Actos in the United States.

ANSWER: TPC admits that, on July 15, 1999, the FDA approved ACTOS® for prescription by licensed physicians in the United States as an adjunct to diet and exercise for the improvement of glycemic control in patients with type 2 diabetes as monotherapy or in combination with a sulfonylurea, metformin, or insulin. TPC further admits that, pursuant to approval by the FDA, TPC has researched and manufactured ACTOS®, TPA has sold, marketed and distributed ACTOS®, Eli Lilly marketed ACTOS® from 1999 to 2006, and TPUSA has marketed ACTOS® for prescription by licensed physicians in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. TPC denies the remaining allegations of paragraph 27.

28. In June 2011, the FDA, as well as the FDA's counterpart agencies in France and Germany, took action against Actos because of revelations of increased incidents of bladder cancer in patients taking Actos. The French agency ordered Actos withdrawn from the market. The Germany agency advised doctors not to put new patients on Actos. The FDA announced that information about an increased risk of bladder cancer will be added to Actos' labeling. However, from the time of Actos' launch in 1999 until the government actions were taken in 2011 and the present, patients who were prescribed Actos developed bladder cancer because the Defendants concealed, and continue to conceal, their knowledge that Actos can cause bladder cancer.

ANSWER: TPC admits that, in June 2011, the French Medicines Agency ("Afssaps") suspended the use of pioglitazone-containing medicines in France while awaiting the outcome of an ongoing European review, and that Germany's Federal Institute for Drugs and Medical Devices ("BfArM") recommended that doctors should not put new patients on pioglitazone. TPC further admits that, on June 15, 2011, the FDA issued a Safety Communication stating that use of ACTOS® for more than one year may be associated with an increased risk of bladder cancer. TPC further admits that the FDA's June 15, 2011 Safety Communication stated that information about this risk will be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines. TPC denies that ACTOS® causes bladder cancer and further denies any remaining allegations of paragraph 28.

29. For example, before its approval by the FDA, drug-induced tumors were observed in rats receiving Actos in levels equivalent to clinical dose.

ANSWER: TPC admits that tumors were observed in the urinary bladders of male rats who received 4mg/kg/day and above of pioglizatone HCl during a two-year carcinogenicity study conducted prior to FDA approval. TPC further admits that results from the two-year carcinogenicity study in rats have been disclosed in the FDA-approved package insert since the FDA's approval of ACTOS® on July 15, 1999. TPC denies the remaining allegations of paragraph 29.

30. Also, in 2005, the results of a three-year study which investigated the impact in total mortality and macrovascular morbidity (i.e., cardiovascular events and outcomes) in Actos,

the PROactive (PROspective PioglitAzone Clinical Trial in Macro Vascular Events) Study, were released. In this study, researchers found a statistically significant increase in the incidents of bladder cancer in patients taking Actos.

ANSWER: TPC admits that the results of the PROactive Study, a three-year clinical trial, were published in 2005. TPC also admits that a goal of the PROactive study was to ascertain whether pioglitazone reduces macrovascular morbidity and mortality in high-risk patients with type 2 diabetes. TPC states that the results of this study speak for themselves. TPC denies that the PROactive study found a statistically significant increase in the incidence of bladder cancer in patients taking ACTOS® and further denies that ACTOS® causes bladder cancer. TPC denies any remaining allegations of paragraph 30.

31. In addition, on September 17, 2010, the FDA issued a Safety Announcement that identified a three-year "liver safety study" performed in regard to Actos that also showed an increased incident of bladder cancer in patients taking Actos. This study was not released or fully identified by the Safety Announcement.

ANSWER: TPC admits that the FDA has stated that a three-year liver safety study demonstrated a higher percentage of bladder cancer cases in patients receiving ACTOS® versus comparators. TPC denies that ACTOS® causes bladder cancer and further denies any remaining allegations of paragraph 31.

32. Moreover, another unpublished study designed to further "address the long-term risk of bladder cancer associated with Actos use" by Defendant Takeda and Kaiser Permanente has also been reported by the FDA. Although intended as a ten-year study, a "planned five-year interim analysis was performed with the data collected from January 1, 1997 through April 30, 2008," and that data showed "the risk of bladder cancer increased with the increasing does and duration of Actos use, reaching statistical significance after 24 months of exposure.

ANSWER: TPC admits that, on September 17, 2010, the FDA issued a Safety Communication announcing that it was reviewing data from an ongoing ten-year epidemiological study by Takeda of patients with diabetes who are members of Kaiser Permanente Northern California designed to evaluate whether ACTOS® is associated with an increased risk of bladder cancer. TPC further admits that, as reported in the FDA's September

17, 2010 Safety Communication, a planned five-year interim analysis of data from this study reported that there was no statistically significant association between ACTOS® exposure and the risk of bladder cancer, but that the risk of bladder cancer increased with increasing dose and duration of ACTOS® use, reaching statistical significance after 24 months of exposure. TPC denies that ACTOS® causes bladder cancer and further denies any remaining allegations of paragraph 32.

33. Furthermore, in 2011, the American Diabetes Association reviewed the adverse event reports made to the FDA concerning Actos between 2004 and 2009. This study concluded that "AERS analysis is consistent with an association between pioglitazone and bladder cancer."

ANSWER: TPC admits that, on April 22, 2011, the American Diabetes Association published a study online that includes the language quoted in paragraph 33. TPC further admits that the study authors retrieved adverse event reports made to the FDA between 2004 and 2009 and that the study authors calculated a reporting odds ratio based on these reports. TPC denies that analysis of adverse event reports constitutes a reliable methodology for assessing causation, denies that ACTOS® causes bladder cancer, and further denies any remaining allegations of paragraph 33.

34. And, on June 15, 2011, the FDA issued another Safety Announcement in regard to Actos in which it unequivocally stated that "use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer." Information abut this risk was ordered to be placed in the *Warnings and Precautions* section of the Actos label.

ANSWER: TPC admits that, on June 15, 2011, FDA issued a Safety Communication stating that use of ACTOS® for more than one year may be associated with an increased risk of bladder cancer. TPC further admits that the FDA's June 15, 2011 Safety Communication stated that information about this risk will be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines. TPC denies that ACTOS® causes bladder cancer and further denies any remaining allegations of paragraph 34.

35. Clearly, the relationship between Actos and bladder cancer has been known, or should have been known, to Defendants. Despite their knowledge, Defendants refused to inform patients, doctors, or the medical community about the risks and put their profits before people.

ANSWER: TPC denies that ACTOS® causes bladder cancer and further denies all allegations of paragraph 35.

36. Actos is one of the top selling drugs for Defendants. It has been listed as one of the top the best selling medication in the United States in various years, and it had global sales of $4.8 billion world-wide last year. Actos also accounts for a significant percentage of Defendants' revenue, despite the significant risk of bladder cancer that it poses.

ANSWER: TPC admits that ACTOS® is one of Takeda's top-selling medications. TPC further admits that Reuters reported, on June 10, 2011, that global sales of ACTOS® amounted to $4.8 billion, accounting for 27 percent of Takeda's revenue. TPC denies that ACTOS® causes bladder cancer and further denies any remaining allegations of paragraph 36.

37. Defendants, through fraud, negligence, misrepresentation, and/or omission have concealed from patients, doctors, the medical community, and the general public the true and significant risks of Actos use. As a result of these actions by Defendants, Plaintiff Samuel Johnson, Jr. was were unaware of and exposed to significant risks, and in fact Plaintiff has been diagnosed with bladder disorders.

ANSWER: TPC denies the allegations of paragraph 37.

FEDERAL REQUIREMENTS

38. Defendants had an obligation to comply with the law in the manufacture, design, and sale of Actos.

ANSWER: TPC states that the allegations of paragraph 38 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 38 are construed as factual allegations directed to TPC, it admits that it complied with its duty under the law at all times. TPC denies the remaining allegations of paragraph 38.

39. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq*.

ANSWER: TPC denies the allegations of paragraph 39.

40. With respect to the prescription drug Actos, Defendants, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for Actos and such deviations are not plainly stated on their labels.

c. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because, among other things, it's labeling is false or misleading.

d. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. The prescription drug Actos does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application,

(d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. The prescription drug Actos is misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Actos cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

k. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Actos.

l. The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug Actos are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.

m. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

n. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

o. The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Actos and other drugs in the same pharmacologically active and chemically related class.

p. The Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop cardiac arrhythmias, while significantly more severe than the other reactions listed in the adverse reactions section, was not listed by Defendant before the other less serious adverse reactions on the labeling of the prescription drug Actos.

q. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual

dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

r. The prescription drug Actos violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

s. The prescription drug Actos violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

t. The prescription drug Actos violates 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

u. The prescription drug Actos violates 21 CFR § 211.165 in that the prescription drug ACTOS fails to meet established standards or specifications and any other relevant quality control criteria.

v. The prescription drug Actos violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Actos were not followed.

w. The prescription drug Actos violates 21 CFR § 310.303 in that the prescription drug Actos is not safe and effective for its intended use.

x. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

y. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug Actos as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.

z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Actos, and evaluating the cause of the adverse event.

aa. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

bb. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

cc. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report followup."

dd. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug Actos or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

ANSWER: TPC denies the allegations of paragraph 40, including all of its subparts.

41. Defendant failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiffs, making the Defendant negligent *per se*.

ANSWER: TPC denies the allegations of paragraph 41.

FACTS REGARDING PLAINTIFFS

42. With Actos, the Defendants negligently produced and manufactured an unreasonably dangerous product and placed it in the stream of commerce. Through the negligence of Defendants and through their acts and/or failures to act, Plaintiffs were prescribed and ingested the prescription drug Actos, which upon information and belief, caused Plaintiffs to suffer physical and mental conditions for which they seek and are entitled to be compensated.

ANSWER: TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 42 regarding plaintiffs' prescription for and ingestion of ACTOS®. TPC denies the remaining allegations of paragraph 42.

43. Plaintiff Lillian Davis suffered bladder injury subsequent to taking Actos.

ANSWER: TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 43 regarding plaintiff Lillian Davis's use of ACTOS® and medical diagnosis. TPC denies that ACTOS® causes bladder cancer and further denies the remaining allegations of paragraph 43.

44. Plaintiff William Coxe suffered bladder injury subsequent to taking Actos.

ANSWER: TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 44 regarding plaintiff William Coxe's use of ACTOS® and medical diagnosis. TPC denies that ACTOS® causes bladder cancer and further denies the remaining allegations of paragraph 44.

45. As a direct and proximate result of using Actos, Plaintiffs suffered general and special damages, past and future pain and suffering, emotional distress, loss of enjoyment of life, inconvenience, disability, disfigurement, increased risk of death, deterioration or disease, fear of death, past and future surgical expenses, hospital bills, doctors' fees, prescription drug costs, the costs of diagnostic tests, and other medical costs and expenses, loss of consortium, loss of society, and/or loss of support, and loss of earning and/or earning capacity.

ANSWER: TPC denies the allegations of paragraph 45.

46. Plaintiffs healthcare providers were at the time of their injuries, unaware, and could not have reasonable known or have learned through reasonable diligence, that such injury directly resulted from the Defendants' negligent and otherwise culpable acts and/or failures to act, omission, and misrepresentations or from Plaintiffs' ingestion of Actos.

ANSWER: TPC denies the allegations of paragraph 46.

47. The Actos ingested by Plaintiffs was designed, manufactured, distributed and sold by Defendants, and was intended to safely and effectively treat type II diabetes, and Defendants represented Actos to be an appropriate product for such purposes.

ANSWER: TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 47 regarding plaintiffs' ingestion of ACTOS®. TPC admits that, pursuant to approval by the FDA, TPC has manufactured ACTOS®, TPA has sold, marketed and distributed ACTOS®, Eli Lilly marketed ACTOS® from 1999 to 2006, and TPUSA has marketed ACTOS® for prescription by licensed physicians in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. TPC further admits that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. TPC denies the remaining allegations of paragraph 47.

48. Plaintiffs used Actos in a proper and reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold.

ANSWER: TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 48.

49. Plaintiffs would not have used Actos had the Defendants properly disclosed the risks associated with this drug.

ANSWER: TPC denies the allegations of paragraph 49.

50. By reason of the foregoing, Plaintiffs have suffered personal injuries which are permanent and lasting in nature; have suffered physical pain and mental anguish, including diminished enjoyment of life; and will require lifelong medical treatment, monitoring and/or medications.

ANSWER: TPC denies the allegations of paragraph 50.

51. Plaintiffs have endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature; suffer physical pain and mental anguish, including diminished enjoyment of life; require

lifelong medical treatment, monitoring and/or medications; and live in fear of developing any of the above named health consequences.

ANSWER: TPC denies the allegations of paragraph 51.

52. By reason of the foregoing, Plaintiffs have been severely and permanently injured, including the risk of premature death, and will require more constant and continuous medical monitoring and treatment than prior to his use of Defendants' drug Actos.

ANSWER: TPC denies the allegations of paragraph 52.

53. Despite have actual notice of the dangerous propensities associated with Actos, prior to the date of Plaintiffs' purchase and use of Actos, the Defendants took inadequate steps to advise consumers or medial providers, including Plaintiffs, of the known dangers of Actos consumption, including but not limited to the increased risk of bladder cancers. The Defendants failed to take adequate steps to ensure that the Actos it sold was safe for public and would function in the manner intended.

ANSWER: TPC denies the allegations of paragraph 53.

54. Even after being made aware of the increased incidents of bladder cancer, Defendants still failed to take all reasonable and necessary steps to ensure that the consuming public, including Plaintiffs, was aware of the increased risk of suffering these cardiac injuries.

ANSWER: TPC denies the allegations of paragraph 54.

55. Defendants were aware of the dangerous properties of Actos described herein, and knew the risks and dangers posed to patients ingesting Actos, and Defendants acted with willful and wanton disregard for the safety of the public, including Plaintiffs'.

ANSWER: TPC denies the allegations of paragraph 55.

56. Despite this knowledge, Defendants have widely promoted the use of Actos as a safe and effective treatment for type II diabetes.

ANSWER: TPC admits that ACTOS® is safe and effective when prescribed and used in accordance with its FDA-approved labeling. TPC denies the remaining allegations of paragraph 56.

57. As a result of Defendants' efforts and actions, the sales of Acts have become an enormous source of profits for Defendants.

ANSWER: TPC states that the term "enormous source of profits" is vague and ambiguous and that TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph pertaining to same. TPC denies any remaining allegations of paragraph 57.

58. Accordingly, the Defendants had a significant financial incentive to suppress, misrepresent, and/or conceal any potential dangers or risks associated with Actos. Defendants maximized profits at the expense of the health of patients taking Actos, including Plaintiffs, and Defendants failed to adequately or appropriately disclose material information relating to the dangers associated with Actos. As a result, users of Actos, including Plaintiffs, were unaware of these dangers, did not have adequate information to know the risks of ingesting Actos and were therefore unable to avoid injury caused by ingesting this defective product.

ANSWER: TPC denies the allegations of paragraph 58.

59. As a direct and proximate result of Defendants' defective design and manufacture, inadequate warnings, fraud, misrepresentation, omission, and other acts as described herein regarding Actos, Plaintiffs sustained injuries.

ANSWER: TPC denies the allegations of paragraph 59.

60. As a result of their ingestion of Actos, Plaintiffs Lillian Davis and William Coxe have sustained the following non-exclusive list of damages:

A. Physical injuries;

B. Past and future emotional distress;

C. Loss of enjoyment of life;

D. Past and future mental pain and suffering;

E. Inconvenience;

F. Past and future pain, suffering and disability;

G. Medical expenses;

H. Other damages to be proven at the trial of this matter.

ANSWER: TPC denies the allegations of paragraph 60, including all of its subparts.

61. As a result of her spouse's ingestion of Actos, Plaintiff Barbara Coxe has sustained the following non-exclusive list of damages:

A. Loss of Consortium;

B. Past and future emotional distress;

C. Past and future pain and suffering;

D. Inconvenience;

E. Medical expenses;

F. Other damages to be proven at the trial of this matter.

ANSWER: TPC denies the allegations of paragraph 61, including all of its subparts.

FRAUDULENT CONCEALMENT

62. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through affirmative misrepresentations and omissions, actively concealed from Plaintiffs, physicians, the medical community, and the general public the true risks associated with Actos.

ANSWER: TPC denies the allegations of paragraph 62.

63. As a result of Defendants' actions, Plaintiffs and physicians were unaware, and could not reasonably have known or have learned through reasonable diligence, that they had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

ANSWER: TPC denies the allegations of paragraph 63.

CLASS ACTION ALLEGATIONS

64. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, Plaintiffs bring this class action for money damages, medical monitoring, and any appropriate declaratory or other relief on behalf of themselves and a class, defined as: All persons in the United States and its territories who ingested Actos from July 15, 1999 to present.

ANSWER: TPC states that the allegations of paragraph 64 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 64 are construed as factual allegations directed to TPC, it admits that plaintiffs purport to bring this action as a class

action for money damages, medical monitoring, and any appropriate declaratory or other relief on behalf of themselves and as a class. TPC denies that this action may be tried as a class action and further denies that plaintiffs' proposed class may properly be certified pursuant to Rule 23 of the Federal Rules of Civil Procedure. TPC denies any remaining allegations of paragraph 64.

65. Excluded from Class are Defendants and any entity in which any Defendants has a controlling interest, and their legal representatives, officers, directors, assignees, and successors. Also excluded from the class is any judge or justice to whom this action is assigned, together with any relative of such judge or justice within the third degree of relationship, and the spouse of any such person.

ANSWER: TPC states that the allegations of paragraph 65 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 65 are construed as factual allegations directed to TPC, it admits that plaintiffs purport to exclude certain individuals from the proposed class. TPC denies that this action may be tried as a class action and further denies any remaining allegations contained in paragraph 65.

66. Actos was taken by millions of people each week, therefore the Class consists of millions of individuals and thousands of entities throughout the United States, making individual joinder impractical, in satisfaction of Rule 23(a)(1).

ANSWER: TPC states that the allegations of paragraph 66 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 66 are construed as factual allegations directed to TPC, they are denied.

67. Plaintiffs' claims are typical of the claims of the Class as required by Rule 23(a)(3), in that Plaintiffs, like all Class members, purchased and/or paid for Actos and ingested Actos.

ANSWER: TPC states that the allegations of paragraph 67 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 67 are construed as factual allegations directed to TPC, it denies that plaintiffs' claims are typical of the claims of

the proposed class. TPC lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 67.

68. Questions of law and fact are common to the Class and predominate over questions affective only individual members, including the following:

a. Whether the alleged conduct by Defendants violated laws as alleged in this Complaint;

b. Whether Defendants engaged in unfair, unlawful and/or fraudulent business practices;

c. Whether Plaintiffs and the Class Members are entitled to equitable and/or injunctive relief;

d. Whether Defendants' unlawful, unfair and/or deceptive practices harmed Plaintiffs and the Class members; and

e. Whether Defendants were unjustly enriched by deceptive practices.

ANSWER: TPC states that the allegations of paragraph 68 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 68 are construed as factual allegations directed to TPC, they are denied.

69. Plaintiffs' claims are typical of the claims of the Class Members, because their claims arise from the same course of conduct by Defendants and the relief sought is common.

ANSWER: TPC states that the allegations of paragraph 69 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 69 are construed as factual allegations directed to TPC, it states that the phrase "course of conduct" is vague and ambiguous. Accordingly, TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 69 pertaining to same. TPC denies any remaining allegations of paragraph 69, and specifically denies that plaintiffs' claims are typical of the claims of the proposed class.

70. Plaintiffs will fairly and adequately represent and protect the interests of all Class Members. Plaintiffs are represented by counsel competent and experienced in both consumer

protection and class action litigation. Plaintiffs and their counsel are committed to the vigorous prosecution of this action on behalf of the Class and have the financial resources to do so. Neither Plaintiffs' nor their counsel has any interests adverse to those of the Class.

ANSWER: TPC states that the allegations of paragraph 70 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 70 are construed as factual allegations directed to TPC, it denies that plaintiffs are adequate representatives of the proposed class. TPC lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 70.

71. Class certification is proper under Fed. R. Civ. P. 23(b)(1)(A), because the prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications with respect to individual Class Members and potentially establish incompatible standards of conduct for Defendants.

ANSWER: TPC states that the allegations of paragraph 71 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 71 are construed as factual allegations directed to TPC, they are denied.

72. Class certification is proper under Fed. R. Civ. P. 23(b)(3), because common issues of law and fact predominate over any questions affecting only individual members of this Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

ANSWER: TPC states that the allegations of paragraph 72 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 72 are construed as factual allegations directed to TPC, they are denied.

73. Plaintiffs know of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action.

ANSWER: TPC states that the allegations of paragraph 73 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 73 are construed as factual allegations directed to TPC, it denies that plaintiffs' claims would be manageable as a class action and denies that this litigation is appropriate for class action resolution. TPC lacks

knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 73.

74. A class action is superior to other methods for the fair and efficient adjudication of this controversy, since joinder of all members is impracticable. Furthermore, because the economic damages suffered by the individual Class Members may be relatively modest, albeit significant, compared to the expense and burden of individual litigation, it would be impracticable for Class Members to seek redress individually for the wrongful conduct alleged herein.

ANSWER: TPC states that the allegations of paragraph 74 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 74 are construed as factual allegations directed to TPC, they are denied.

75. Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants and promotes consistency and efficiency of adjudication.

ANSWER: TPC states that the allegations of paragraph 75 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 75 are construed as factual allegations directed to TPC, they are denied.

COUNT ONE

LOUISIANA PRODUCTS LIABILITY ACT

76. Plaintiffs hereby restate and reallege each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.

ANSWER: TPC incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

77. Actos proximately caused damages to the Plaintiffs, which damage was caused by a characteristic of the product that rendered it unreasonably dangerous arising from a reasonably anticipated use of the product by Plaintiffs, thus rendering Defendant liable to Plaintiffs pursuant to LSA R.S. 9:2800.54

ANSWER: TPC denies the allegations of paragraph 77.

78. Actos is unreasonably dangerous for the following reasons:

A. It is unreasonably dangerous in construction or composition as provided in LSA R.S. 9:2800.55

B. It is unreasonably dangerous in design as provided in LSA R.S. 9:2800.56.

C. It is unreasonably dangerous because an accurate warning about the product was not provided as required by LSA R.S. 9:2800.57

D. It is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as provided in LSA R.S. 9:2800.58.

ANSWER: TPC denies the allegations of paragraph 78, including all of its subparts.

79. The characteristics of Actos that render it unreasonably dangerous under LSA 9:2800.55, LSA R.S. 9:2800.56, and LSA R.S. 9:2800.57 *et seq*. existed at the time the product left the control of the manufacturer or resulted from a reasonably anticipated alteration or modification of the product.

ANSWER: TPC denies the allegations of paragraph 79.

80. For all the reasons alleged herein, Actos was unreasonably dangerous in design at the time the product left the manufacturer's control in that:

A. There existed an alternative design for the product that was capable of preventing the Plaintiffs' damages; and

B. The likelihood that the product's design would cause the Plaintiffs' damages and the gravity of those damages outweigh the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

ANSWER: TPC denies the allegations of paragraph 80, including all of its subparts.

81. For all the reasons alleged herein, Actos was unreasonably dangerous because an adequate warning about the product had not been provided and at the time the product left the manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide adequate warning that such characteristic and its dangers to users of the product.

ANSWER: TPC denies the allegations of paragraph 81.

82. Further, Defendants, after the product left its control, acquired knowledge of the characteristic of the product that may cause damage and the danger of such characteristic (or, alternatively, Defendants would have acquired such knowledge if it had acted as reasonable prudent manufacturers), and thus are liable for damages suffered by Plaintiffs which arose as a consequence of Defendants' failure to use reasonable care to provide an adequate warning of such characteristic and its dangers to users.

ANSWER: TPC denies the allegations of paragraph 82.

83. Defendants expressly warranted to the market, including Plaintiffs, by and through statements made by Defendants or its authorized agents or sales representatives, orally and in publications, package inserts, advertisements and other materials to the health care and general community, that Actos was safe, effective, fit and proper for its intended use.

ANSWER: TPC denies the allegations of paragraph 83.

84. In using Actos, Plaintiffs and their physicians relied on the skill judgment, representations, and foregoing express warranties of the Defendants. These warranties and representations proved to be false because the product was not safe and was unfit for the uses for which it was intended.

ANSWER: TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 84 regarding plaintiffs' use of ACTOS®. TPC denies the remaining allegations of paragraph 84.

COUNT TWO

VIOLATION OF WARRANTY OF REDHIBITION

85. Plaintiffs hereby restate and reallege each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.

ANSWER: TPC incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

86. Defendants were aware of the substantial risks from using Actos but failed to fully disclose the same.

ANSWER: TPC denies the allegations of paragraph 86.

87. Defendants, as the manufacturers of Actos, are deemed to be aware of its redhibitory defects pursuant to LSA-C.C. Article 2545.

ANSWER: TPC states that the allegations of paragraph 87 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 87 are construed as factual allegations directed to TPC, they are denied.

88. Had Plaintiffs been aware of the defects contained in Actos, Plaintiffs would not have purchased or ingested Actos. This characteristic rendered it unfit for its intended purposes.

ANSWER: TPC lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 88 regarding plaintiffs' prescription for and ingestion of ACTOS®. TPC denies the remaining allegations of paragraph 88.

89. Defendant is liable to Plaintiffs and each member of the Class under the theory of redhibition as a consequence of the sale to Plaintiffs and the Class of a product unfit for its intended use.

ANSWER: TPC denies the allegations of paragraph 89.

90. Plaintiffs and the Class are entitled to the return of any purchase price paid, including but not limited to, insurance co-payments, interest on these amounts from the date of purchase, attorneys fees and costs, pecuniary and non-pecuniary damages, as well as any other legal and equitable relief to which Plaintiffs may be entitled.

ANSWER: TPC denies the allegations of paragraph 90.

91. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand trial by jury on all issues so triable.

ANSWER: TPC states that the allegations of paragraph 91 constitute legal conclusions to which no response is required. To the extent that the allegations of paragraph 91 are construed as factual allegations directed to TPC, it admits that this action may be tried by a jury.

TPC'S SEPARATE OR AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that one or more of the following additional defenses should be available to TPC in this matter. TPC accordingly reserves the right to assert these separate and additional defenses. Upon completion of discovery, if the facts warrant, TPC

may withdraw any of these additional defenses as may be appropriate. TPC further reserves the right to amend its Answer and defenses, and to assert additional defenses and other claims, as this matter proceeds.

Further answering, and by way of additional defense, TPC states as follows:

1. Plaintiffs' Complaint fails to state a claim upon which relief can be granted for compensation for medical monitoring.

2. Plaintiffs' Complaint fails to state a claim upon which relief can be granted on a class-wide basis.

3. Plaintiffs' class action claims fail because a class action is an inappropriate vehicle for the prosecution of Plaintiffs' claims. Plaintiffs' claims do not meet the criteria for class certification and may not be pursued as a class action pursuant to Federal Rule of Civil Procedure 23.

4. Plaintiffs' class action claims fail because Plaintiffs are inadequate representatives of the proposed putative class.

5. Plaintiffs' class action claims fail because the questions of law and fact presented in the Complaint are not common to the putative class.

6. Plaintiffs' class action claims fail because questions of law and fact common the members of the putative class do not predominate over questions affecting only individual members.

7. Plaintiffs' class action claims fail because a class action is not superior to other available methods for the fair and efficient adjudication of the controversy.

8. Plaintiffs' Complaint fails to state a claim for unlawful conduct under any state consumer protection statute, because TPC completely complied with the applicable law in connection with the distribution of Actos.

9. Plaintiffs' claims for injunctive or other equitable relief are barred because there is an adequate remedy at law.

10. Plaintiffs' claims for injunctive or other equitable relief are barred as moot in whole or in part because the alleged injury ceased when Plaintiffs stopped taking Actos.

11. Plaintiffs' Complaint against TPC fails to state a claim upon which relief may be granted.

12. Plaintiffs' alleged injuries were proximately caused by circumstances, events, or persons over whom TPC had no authority or control and for which TPC is not answerable in damages to Plaintiff.

13. Plaintiffs assumed the risks, if any, inherent in the use and continued use of ACTOS®.

14. To the extent Plaintiffs' claims were caused by the actions, omissions, or products of persons or entities over whom TPC has no dominion, authority, or control, TPC is entitled to have its liability to the Plaintiffs, if any, reduced as a result of the fault or negligence of said persons or entities, pursuant to governing law.

15. Plaintiffs' recovery is barred and/or should be reduced under the applicable law because of Plaintiffs' contributory negligence or fault and/or comparative negligence or fault under Louisiana Civil Code Article 2323.

16. The alleged injuries sustained by Plaintiffs, if any, were caused, in whole or in part, by pre-existing physical, medical, and/or physiological conditions for which TPC has no legal responsibility.

17. Plaintiffs' alleged injuries, if related to Plaintiffs' use of ACTOS®, were caused by an unforeseeable material and substantial alteration, change, improper handling, or misuse of the product after it left the control of TPC.

18. The New Drug Application for ACTOS® was approved by the FDA under the applicable statute, 21 U.S.C. § 301 et seq., and regulations promulgated thereunder. Compliance with such statutes and regulations by Takeda demonstrates that ACTOS® was safe and effective and not unreasonably dangerous and, further, preempts and bars Plaintiffs' claims against TPC. Compliance with such statutes and regulations also demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of this prescription drug, and that it was neither defective nor unreasonably dangerous.

19. Plaintiffs' claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the pervasive federal regulation of prescription drug manufacturing, testing, marketing, and labeling, and the FDA's specific determinations regarding ACTOS® and other drugs in its class.

20. All labeling for ACTOS® has been approved by the FDA under the applicable statute, 21 U.S.C. § 301 et seq., and regulations promulgated thereunder. Plaintiffs' claims are preempted by federal law pursuant to the Supremacy Clause of the United States Constitution to the extent Plaintiffs assert that state law required changes to the FDA-approved labeling that the FDA itself would not have approved. Plaintiffs' claims also are preempted by federal law pursuant to the Supremacy Clause of the United States Constitution because they would obstruct the federal regulation of drug labeling and frustrate the achievement of congressional objectives.

21. To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

22. Plaintiffs' claims against TPC are barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited, to Section 402A, comment k.

23. Plaintiffs' claims are barred, in whole or in part, because the pharmaceutical product at issue provides net benefits for a class of patients within the meaning of Restatement (Third) of Torts: Products Liability § 6 cmt. f.

24. TPC gives notice that to the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Complaint, TPC intends to rely upon same in defense of this action.

25. The claims in the Complaint are barred in whole or in part by the learned intermediary doctrine. Any warnings which were given were transmitted to the prescribing health care provider and Takeda's only obligation is to warn the prescribing health care provider, which obligation was fulfilled.

26. Plaintiffs' Complaint fails to state a claim upon which relief can be granted against TPC under, among other provisions, La. Rev. Stat. § 9.2800.59, in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing, and sale of ACTOS®, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art, and the applicable standard of care based upon available medical and scientific knowledge.

27. Plaintiffs' claims are barred because ACTOS® was neither defective nor unreasonably dangerous in its design, manufacture or marketing and were reasonably safe and reasonably fit for its intended uses, thereby barring Plaintiffs' recovery.

28. The warnings and instructions accompanying ACTOS® at the time of the occurrence or injuries alleged by Plaintiffs were legally adequate warnings and instructions.

29. Plaintiffs' claims are barred, in whole or in part, by prescription, preemption, and/or the applicable statutes of limitations and/or repose.

30. Plaintiffs' claims against TPC are barred, in whole or in part, by laches, waiver, and/or estoppel.

31. Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' failure to mitigate alleged damages.

32. The injuries and damages claimed by Plaintiffs, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of TPC was not the proximate and/or competent producing cause of such alleged injuries and damages.

33. Any claims by Plaintiffs relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government.

34. The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including TPC.

35. Plaintiffs' claims are barred because the benefits of ACTOS® outweigh the risks, if any, that might be associated with the products.

36. Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement, or restitution.

37. Plaintiffs' claims are barred in whole or in part because the commercial speech relating to ACTOS® was not false or misleading and is protected under the First Amendment to the United States Constitution and the Louisiana Constitution.

38. Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

39. Plaintiffs cannot state a claim with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiffs is subject to the exclusive regulation of the FDA.

40. This Court should abstain from adjudicating Plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

41. If ACTOS® was unsafe (which TPC denies), Plaintiffs' claims are barred because ACTOS® was unavoidably unsafe.

42. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part from collateral sources.

43. To the extent that Plaintiffs' Complaint seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under applicable law.

44. To the extent that Plaintiffs' claims have been settled or Plaintiffs will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of TPC, if any, should be reduced accordingly.

45. Plaintiffs' claims may be barred, in whole or in part, due to res judicata, collateral estoppels, or by release of claims.

46. Plaintiffs' complaint fails to join indispensable parties necessary for the just adjudication of this matter.

47. Plaintiffs' Complaint fails to state a claim for fraud, misrepresentation, or suppression, and fails to allege the circumstances constituting fraud with the particularity required by the Federal Rules of Civil Procedure.

48. Plaintiffs did not detrimentally rely on any labeling, warnings, or information concerning ACTOS®.

49. Applicable law does not recognize a post-sale duty to warn in the present circumstances. Accordingly, the Complaint fails to state a claim upon which relief may be granted for inadequate post-sale marketing or post-sale duty to warn.

50. Plaintiffs' alleged injuries and damages, if any, were the result of an idiosyncratic reaction which TPC could not reasonably foresee.

51. Plaintiffs, or Plaintiffs' physicians, were aware or should have been aware of any potential hazards reported to be associated with the use of ACTOS® and appreciated or should have appreciated these potential hazards based, in part, on the directions, information, and warnings provided by Takeda and others generally available in the medical and scientific literature. Therefore, TPC had no duty to warn of any alleged danger or defect.

52. Plaintiffs are barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by the Plaintiffs without substantially impairing the usefulness or intended purpose of the product.

53. Plaintiffs' claims are barred because ACTOS® was consistent with and exceeded consumer expectations.

54. Plaintiffs' claims for breach of warranty are barred because Plaintiffs failed to give timely notice of any alleged failure.

55. TPC did not sell or distribute the prescription drug ACTOS® directly to Plaintiffs, and Plaintiffs did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiffs' claims are therefore barred by lack of privity between Plaintiffs and TPC.

56. Any warranties made by TPC to Plaintiffs were disclaimed.

57. Plaintiffs' claims for breach of warranty, express or implied are barred by the applicable provisions of the Louisiana Uniform Commercial Code.

58. Any claim for breach of express warranty must fail because Plaintiffs failed to allege any representation about the product at issue giving rise to an express warranty.

59. Any claim for breach of implied warranty fails because the product at issue was used for its ordinary purpose.

60. Any claim for breach of warranty fails because Plaintiffs failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty.

61. Plaintiffs' claims purportedly asserted under statutes and regulations relating to prescription drugs fail, in whole or in part, because these statutes and regulations do not contain or create any private cause of action.

62. TPC had a good faith belief in the lawfulness of its actions.

63. To the extent that Plaintiffs assert claims against TPC based on theories of liability not provided for in the Louisiana Products Liability Act, those claims are barred. La. Rev. Stat. § 9:2800.51, *et seq.*

64. To the extent that Plaintiffs assert claims against TPC based on theories of liability or elements of damages provided in the Louisiana Products Liability Act, Plaintiffs have failed to allege facts that would satisfy the applicable burdens of proof and/or overcome the defenses available under the Louisiana Products Liability Act, La. Rev. Stat. §9:2800.51, *et. seq.*

65. To the extent they are not otherwise specifically set forth herein, TPC adopts and incorporates by reference all affirmative defenses set forth in the Louisiana Products Liability Act, La. Rev. Stat. 9:2800:51, *et seq*.

66. With regard to each and every cause of action, Plaintiffs are not entitled to attorneys fees as a matter of Louisiana law.

67. With regard to each and every cause of action, Plaintiffs are not entitled to recovery for strict liability under Louisiana law.

68. Under Louisiana Civil Code Articles 2323 and 2324, TPC is not liable for more than its own degree of fault, if any, and is not solidarily liable with other persons or entities for damages attributable to the fault of such persons or entities.

69. Plaintiffs fail to state a claim for redhibition under La. Civ. Code Art. 2520, *et seq.*.

70. TPC adopts and incorporates by reference herein any affirmative defenses that may be raised by any other Defendant who is in or may be joined to this action.

71. TPC is entitled to the benefit of all defenses and presumptions provided by the procedural and substantive law of state and federal law.

72. TPC reserves the right to modify, clarify, amend, or supplement these separate or affirmative defenses as discovery proceeds in this case.

JURY DEMAND

TPC hereby demands a trial by jury by the maximum number of jurors permitted by law on all issues so triable.

PRAYER

WHEREFORE, TPC requests that this Court enter judgment in its favor and against Plaintiffs on all counts and allegations of the Complaint and that the Court award TPC its costs and such other relief as it deems just and proper.

DATED: July 25, 2012

Respectfully submitted,

By: */s/ Jaimme A. Collins*
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Counsel for Takeda Pharmaceutical Company Limited

CERTIFICATE OF SERVICE

I hereby certify that on July 25, 2012, I electronically filed the foregoing Answer and Separate or Affirmative Defenses of Takeda Pharmaceutical Company Limited to Plaintiffs' Class Action Complaint with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to all parties of record by operation of the Court's electronic filing system.

/s/ Jaimme A. Collins
Jaimme A. Collins